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No. 06-1498

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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER, INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTIONS PRESENTED

Michigan's product liability law provides a complete defense to pharmaceutical manufacturers who market their products in compliance with requirements imposed on them by the Food and Drug Administration ("FDA"). A proviso to that defense, however, permits it to be overcome if a product liability plaintiff proves that a manufacturer "withholds from or represents to [FDA] information concerning the drug that is required to be submitted under the federal food, drug and cosmetics act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5). This Court has previously held that a state common law action premised on "fraud on the FDA" allegations virtually identical to the Michigan proviso is constitutionally preempted. *Buckman Co. v. Plaintiffs Legal Comm.*, 531 U.S. 341 (2001). Nevertheless, the court below held, in direct conflict with an earlier Sixth Circuit ruling, that constitutional preemption did not foreclose litigation of such alleged "fraud on the FDA" under the Michigan statute when fraud was a necessary, but not sufficient, element of plaintiff's case. The question presented therefore is:

Whether a product liability remedy under state law requiring adjudication of "fraud on the FDA" as an element of plaintiff's case can withstand a preemption challenge under *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001).

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. Member companies are the source of a majority of all new medicines that are discovered and marketed. New medicines accounted for 40% percent of the lifespan increase between 1986 and 2000. *See* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 21 (Nat'l Bureau of Econ. Research, Working Paper No. 9754, 2003). In the past decade alone, PhRMA's members invested approximately $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2007* 42 (2007).

The New Drug Approval review process of the Federal Food and Drug Administration ("FDA") is thorough and comprehensive. Only one of every 10,000 potential medicines investigated by PhRMA's members makes it through the research and development pipeline and is approved for patient use by FDA. Winning FDA approval, on average, takes 15 years of research and development and "costs over $800 million." *See* PhRMA, *What Goes Into the Costs of Prescription Drugs . . . and Other Questions About Your Medicine* 10 (2005). Potential new medicines pass through a series of crucial, FDA-supervised, stages on their way from research laboratories to the pharmacy shelf. *See* 21 C.F.R. § 312 *et seq.* Moreover, FDA has essentially plenary regulatory authority over the

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1. Pursuant to Rule 37.1 of the Rules of the Supreme Court of the United States, Amicus states that no counsel for any party to this case authored this brief, in whole or in part, and no person or entity other than Amicus, its members, or its counsel, has made any monetary contribution to the preparation or submission of this brief. Amicus has sought and has obtained written consent from counsel to both parties to submit this amicus brief.

pharmaceutical industry, including not only initial drug approval, but labeling and advertising as well. FDA has the authority and the means to redress violations of the Federal Food Drug and Cosmetics Act ("FDCA"), including fraud on the agency. *See* 21 U.S.C. § 355.

PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues. PhRMA has a particular interest in cases involving possible state law interference with the comprehensive public health regulatory regime for prescription drugs administered by the FDA. PhRMA supports and endorses this Court's safeguarding of the "inherently federal" relationship between FDA and pharmaceutical manufacturers against state law intrusion arising from alleged fraud on the FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). PhRMA is concerned that the Second Circuit's decision in this case, unless reviewed and reversed, would undermine this Court's decision in *Buckman* and conflict with the Sixth Circuit's more sound resolution of the same preemption issue in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004).

The Second Circuit's opinion would effectively require Michigan product liability plaintiffs to litigate the issue of "fraud on the FDA" under Michigan law. Such litigation by private parties under state law would oust FDA from the exclusive, discretionary enforcement role Congress conferred upon it under FDCA. Congress entrusted to FDA the sole responsibility to police fraud on the agency and provided FDA with the tools to set and patrol appropriate bounds on manufacturer disclosure. By allowing fraud on the FDA to be regulated under state law, the Second Circuit's decision will introduce unnecessary uncertainty into a field that demands regulatory stability. Fraud-on-the-FDA litigation, even apart from permitting burdensome and intrusive discovery, thus would force PhRMA members to flood FDA with unnecessary information to protect themselves against determinations that, in the view of state judges and juries, such information was required to be submitted to FDA and

would have influenced FDA's regulatory judgments. Most fundamentally, such litigation would encourage further state law encroachment on the federal regime with consequent overlapping and conflicting regulatory mandates that can deter the beneficial use of existing medicines and the development of new ones.

INTRODUCTION

The petition addresses a direct and acknowledged conflict between two federal courts of appeal on an important issue of federal preemption. Michigan's product liability law provides a complete defense to pharmaceutical manufacturers from liability for injuries caused by drug products distributed and labeled consistent with FDA regulatory approval. Mich. Comp. Laws § 600.2946(5). The law provides, however, that this statutory defense can be overcome if a plaintiff proves that the relevant FDA approval was fraudulently obtained. *Id.* § 600.2946(5)(a). Petitioner argued to the Second Circuit that this "exception" to the FDA compliance defense was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which this Court held that state law "fraud-on-the-FDA" liability claims conflicted with FDCA and therefore were preempted. The Second Circuit, finding *Buckman* distinguishable from the present case for several reasons, rejected Petitioner's preemption claim. The ruling is incorrect.

The Second Circuit wrongly invoked a presumption against preemption—one that some courts have applied to traditional product liability claims—to tip the scales against preemption of litigating fraud on the FDA under Michigan law. There is good reason to conclude that the presumption against preemption is inapplicable to conflict preemption generally, and obstacle preemption in particular. *See, e.g., Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002). Regardless, *Buckman* makes clear that any such presumption is inapplicable to fraud-on-the-FDA claims because of the "inherently federal" relationship between FDA and pharmaceutical manufacturers which "originates from, is governed by, and terminates according to federal law."

Buckman, 531 U.S. at 347. A presumption favoring preservation of historic state regulatory interests has no applicability to state superintendence of the relationship between a federal agency and the industry it regulates.

The Second Circuit also erred in ruling that, because Respondents' causes of action were not grounded exclusively on a fraud-on-the-FDA claims theory, *Buckman* did not control. The conflict in *Buckman* arose from the state's assertion of power to review the regularity of federal approval actions under state law. Just as in *Buckman*, liability under the Michigan statute in this case turns on Respondents' ability to prove as a matter of state law that FDA approval was obtained through fraud. This determination would require the same speculation and interference with FDA's regulatory objectives that led to the preemption ruling in *Buckman*. *See id.* at 354 (Stevens, J., concurring).

The Second Circuit ignored the practical difficulties arising from allowing state courts to litigate fraud-on-the-FDA that were central to this Court's decision in *Buckman*. Permitting this uniquely federal question to be litigated under state law would defeat the exclusive role Congress granted to FDA in policing fraud; indeed, all such issues should be raised directly to the agency that Congress charged with determining whether fraud had occurred in the federal approval process. Denying preemption thus could produce cases where FDA and state courts reach contrary determinations on the same question of fraud. This is an untenable result that would allow states to "second-guess[] the FDA's decisionmaking" and "overburden[] its personnel." *Id.* Moreover, increased pressure on the application process and state oversight of the FDA approval process would force drug manufacturers to adjust their behavior by flooding FDA with additional information the agency is unlikely to deem useful or necessary. *See id.* at 351. Such a regime would ultimately overwhelm FDA's resources and undermine the agency's ability to protect public health.

As the Second Circuit acknowledged, its decision stands in direct conflict with the Sixth Circuit's application of *Buckman* to the same Michigan statute. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). The Sixth Circuit correctly held that, although the fraud-on-the-FDA issue arose in a slightly different posture from *Buckman* under the Michigan statute, *Buckman* preempted litigation of fraud-on-the-FDA under state law and thus limited any application of fraud to cases where the federal authority had made its own prior fraud determination. As here, the *Garcia* plaintiff sought to prove under state law that fraud had occurred, and the court properly held that this claim was preempted under *Buckman*, requiring the plaintiff's underlying claim to be dismissed in accordance with the remaining provisions of Michigan law. *See id.* at 965.

The Court should resolve this square conflict. The issue of fraud-on-the-FDA not only arises under Michigan statutory law and an essentially identical Texas law, it controls whether punitive damages will be allowed against drug manufacturers in at least six other states. Evaluation of these statutes has produced decisions that support *Buckman* preemption and conflict with the decision below. *See, e.g., Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166 (D. Ariz. 2005); *Ledbetter v. Merck & Co.*, No. 05-59499, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 19, 2007); *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266 (M.D. Tenn. Feb. 27, 2007).

Moreover, the impact of *Buckman* has spread well beyond the FDA arena. *See, e.g., Nathan Kimmel, Inc., v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002); *Zwiercan v. Gen. Motors Corp.*, No. 3235 (June Term), 2002 WL 31053838 (Pa. Com. Pl. Sept. 11, 2002); *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704 (E.D. Tenn. 2001). Reversing the decision below therefore would both settle the *Buckman* issue in the FDA context and strengthen the federal preemption that rightly protects federal agency actions from being second-guessed under state law in a variety of federal regulatory areas and in a large number of cases.

REASONS FOR GRANTING THE PETITION

I. Certiorari Should Be Granted To Resolve An Acknowledged Split Between The Courts Of Appeal Of The Second And Sixth Circuit On An Important Issue Of Federal Preemption.

The Second Circuit, in the case at bar, confronted a products liability claim against a pharmaceutical manufacturer under Michigan law. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 93 (2d Cir. 2006). Michigan law effectively allows pharmaceutical manufacturers a complete defense against product liability when their products are distributed in accordance with FDA regulatory requirements. *See* Mich. Comp. Laws § 600.2946(5). The statutory defense does not apply, however, where the manufacturer "[i]ntentionally withholds from or misrepresents to [FDA] information concerning the drug that is required to be submitted under [FDCA] and the drug would not have been approved, or [FDA] would have withdrawn approval for the drug if the information were accurately submitted." *Id.* § 600.2946(5)(a).

The validity of this "fraud-on-the-FDA" exception to the Michigan statutory defense depends on the force and meaning of this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the plaintiff brought a state law cause of action, which alleged that consultant to a medical device manufacturer had made "fraudulent representations" to FDA during the approval process. *See id.* at 343. According to the plaintiffs, "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* at 344. This Court unanimously ruled that state law "fraud-on-the-FDA" product liability causes of action conflicted with, and "therefore [were] impliedly preempted by, federal law." *Id.* at 348; *id.* at 353 n.1 (Stevens, J., concurring) (agreeing that "federal law 'pre-empts' this state law fraud-on-the-FDA claim").

In this case, the Second Circuit rejected the applicability of *Buckman* and ruled that the exception to the Michigan statutory defense, which hinged on whether FDA had been defrauded in

the application process, was not preempted. *See Desiano*, 467 F.3d at 93 (finding a "meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law"). As explained below, the Second Circuit reached this result for three principal reasons that do not provide a sufficient basis for distinguishing *Buckman* from the present case.

First, the court found that, because the Michigan statute made fraud on the FDA an element of product liability claims, a presumption against preemption applied. *See id.* at 94 ("[T]he cause of action . . . cannot reasonably be characterized as a state's attempt to police fraud against the FDA . . . . The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law."). At the outset, it remains unsettled whether the presumption against preemption even applies in the implied preemption context. *Compare Pharm. Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1206 (11th Cir. 2002) ("In this circuit, a state statute is generally not entitled to a presumption against implied conflict preemption."), *with Frank Bros, Inc. v. Wisconsin Dep't of Transp.*, 409 F.3d 880, 885 (7th Cir. 2005) ("We presume that, in all circumstances, Congress does not intend to supplant state law."). This Court has expressly acknowledged that whether the presumption applies in the context of implied conflict preemption remains an open question. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) ("We leave for another day a consideration in this context of a presumption against preemption.").

In fact, there is good reason to conclude that the presumption is inapplicable to the obstacle preemption framework. As the Court has explained, artificially narrowing the reach of a federal statute, through the invocation of the presumption, makes little sense in such circumstances: "[O]ne can assume that Congress or an agency ordinarily would not intend to permit a significant conflict . . . . To insist on a specific expression of agency intent to pre-empt, made after notice-and-comment rulemaking, would be in certain cases to tolerate conflicts that an agency,

and therefore Congress, is most unlikely to have intended." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 885 (2000). A presumption that requires a *narrow* reading of a congressional enactment has no place in an examination of whether a state law imposes an obstacle to the accomplishment of federal objectives. *See id.* ("The dissent, as we have said, apparently welcomes that result, at least where 'frustration-of-purpos[e]' pre-emption by agency regulation is at issue. We do not." (internal citations omitted)).

In any event, the court's invocation of the presumption cannot be squared with *Buckman*. Whether the presumption applies cannot turn, as the Second Circuit would have it, on whether the "legislative scheme" generally seeks to police fraud against the FDA or whether the state law at issue vindicates some broader objective. Under such a view, states could make fraud on the agency a convenient tool for asserting power to set aside or ignore relevant federal requirements so long as a finding of irregularity was not the sole basis for liability under state law. *Buckman* is not so myopic. *See* Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. of Tort Law, Issue 1, Article 5 (2006) (criticizing *Desiano* for making "a huge deal out of the pedigree of the state law cause of action when the dominant concern of the Supreme Court was the entanglement of the FDA in state litigation, which remains the same no matter how state law tees up the plaintiff's cause of action").

Rather, *Buckman* makes clear that the presumption does not apply, not because fraud-on-the-FDA was the basis for liability, but because fraud-on-the-FDA litigation would allow state court judges and juries to invade and impose added and potentially inconsistent requirements on the relationship between FDA and drug manufacturers. *See Buckman*, 531 U.S. at 348 (explaining that the "conflict stems from the fact that the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate

balance of statutory objectives"). In short, "the relationship between a federal agency and the entity it regulates is *inherently federal in character* because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347 (emphasis added). Accordingly, the presumption does not apply in *any* case where state law permits the issue of fraud-on-the-FDA to be litigated. This is just such a case.

The Second Circuit's invocation of the presumption infected the court's mistaken ruling throughout. *See Desiano*, 467 F.3d at 95 & n.7 (framing its refusal to allow Congress "without any explicit expression of intent . . . to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers" as "another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case"); *see also id.* at 96 ("Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." (citations omitted)); *id.* at 98 ("The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims."). Correcting that error alone warrants a grant of certiorari to reverse the decision below.

Second, the court below claimed that, unlike in *Buckman*, the plaintiffs' causes of action were not grounded exclusively on a fraud-on-the-FDA theory. *See id.* at 95 (concluding that "unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA" and that "plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime"). This is an overly narrow reading of *Buckman*. Again, *Buckman* did not find preemption because the fraud-on-the-FDA determination was sufficient to obtain a judgment against the defendant. Rather, *Buckman* made clear that preemption followed from the necessity of proving fraud on the FDA as part of the case. Here, just as in *Buckman*, liability under the

Michigan statute turns on whether the plaintiff can establish that the defendants obtained FDA approval through fraud. *See id.* at 95. And, in both *Buckman* and the present case, that determination would require a speculative assessment as to whether FDA would have required the information at issue to have been submitted and whether FDA would have reached a different regulatory decision based on that information.

Hence, Michigan law fosters the very type of state interference that *Buckman* concluded was preempted under federal law. *See Buckman*, 531 U.S. at 352 ("[T]he existence of these federal enactments is a critical element in their case."); *id.* at 354 (Stevens, J., concurring) ("This would be a different case, if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market."). Indeed, the Second Circuit's interpretation of *Buckman* appears to allow a state judge or jury to find fraud on the FDA even where FDA had specifically ruled that no such fraud had occurred. *Compare Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 9 (Cal. 2004) (preempting state law cause of action where "FDA has rejected plaintiff's claim that his data justify a different warning, and defendants do not claim to have any additional data").[2] This cannot be correct: "Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply." *Ledbetter v. Merck & Co.*, No. 05-59499, 2007 WL 1181991 (Tex. Dist. Ct. Harris County Apr. 20, 2007); *see also* Epstein, *supra*, at 7 (explaining that *Buckman* "held unanimously . . . that no tort plaintiff could bring any tort action that made an evaluation of FDA conduct the subject of state court proceedings, with their extensive pre-trial discovery by way of both interrogatories and deposition").

2. In so doing, the Second Circuit's decision thus discourages citizen petitions to FDA, *see* 21 C.F.R. § 10.30, which unlike state law suits, allow the agency with the expertise and institutional knowledge to reach an informed decision about alleged fraud.

Third, the Second Circuit blatantly disregarded the practical effects of state court fraud-on-the-FDA litigation that drove this Court's decision in *Buckman*. *See Desiano*, 467 F.3d at 97. Fraud-on-the-FDA litigation under state law interferes with important federal policies and obstructs FDA's ability to fulfill its congressional mandate. Foremost, allowing state courts to pursue "fraud-on-the-FDA" questions undermines the enforcement flexibility Congress entrusted to FDA. *See Buckman*, 531 U.S. at 341-42. FDA has a variety of tools at its disposal to police fraud on the agency in the approval process. *See id.* at 349 (explaining that FDA is "empowered to investigate suspected fraud" and that federal law includes "various provisions aimed at detecting, deterring, and punishing false statements made during . . . approval processes"). In responding to fraud, FDA, may, in its unfettered discretion, seek injunctive relief, 21 U.S.C. § 332, civil penalties, *id.* § 333(g)(1)(A), or criminal prosecution, *id.* § 333(a). FDA may also seize a medical device, *id.* § 334(a)(2)(D), or have a prescription drug removed from the marketplace, *id.* § 334(a)(1). The availability of this range of regulatory options is central to FDA's mission: "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349.

State court fraud-on-the-FDA litigation also would undermine FDA's ability to make operative the scientific determinations that Congress entrusted to the agency.[3] In determining the scope of a manufacturer's required disclosures and how any item of information affects the ultimate determination whether a drug is safe and effective under labeled conditions of use, FDA exercises critical scientific judgment

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3. FDA's new drug approval ("NDA") process is extensive. *See* 21 U.S.C. § 355(b). The manufacturer must submit a litany of information and scientific data relating to the drug's safety and efficacy. *Id.* § 355(b)(1); 21 C.F.R. § 314.50 ("The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.").

taking into account the entire file and, often, the advice of expert advisory committees. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("Under the Act and FDA regulations, the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." (citation omitted)). FDA has made this clear in congressional testimony:

> Every time the scientists on our staff allow a new drug to come on the market, they have to take the sum total of scientific knowledge that they can muster about the drug, and reach a conclusion as to whether or not the good that that drug will do, the lives it will save or the suffering that it will prevent, outweighs the known side effects.

Drug Industry Antitrust Act: Hearing Before the Antitrust Subcomm. on Antitrust, 87th Cong. 135 (1962).[4]

Indeed, FDA's scientific judgments warrant considerable deference. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("The determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations" and is "peculiarly suited to initial determination by the FDA."); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1043 (10th Cir. 2006), *cert. denied*, 127 S. Ct. 2295 (2007) ("The review of scientific literature is properly in the province of the FDA, to which this Court grants deference based on its expertise."); *Schering Corp. v. FDA*, 51 F.3d 390, 399

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4. Juries thus would be forced to predict whether the information allegedly withheld during the NDA approval process was material to FDA's approval. Juries simply are not in a position to evaluate the scientific "materiality" of information not submitted to FDA. *Cf. Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir. 1995) ("Given the FDA's central role in reviewing and approving devices under the MDAs, the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction.").

(3d Cir. 1995) ("[FDA's] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us."). Yet, under the Second Circuit's decision, FDA decisions would be subject to limitless second-guessing from state judges and juries ill-equipped to make the scientific and technical judgments necessary to determine whether fraud was material. This burden would clearly obstruct FDA's execution of federal responsibilities under FDCA.

Finally, state superintendence over federal fraud claims would impose burdens on potential applicants and on FDA that directly contradict the expressed will of Congress. *See Buckman*, 531 U.S. at 350 ("[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA."). That is, plaintiffs under state law will seek to expand the category of information "required to be submitted" to its outer limits. This necessarily will draw a reaction from drug manufacturers. *See id.* at 351 ("Applicants would . . . have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."). Fraud-on-the-FDA claims would cause applicants "to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.*

FDA clearly would be overwhelmed if every piece of potential raw data or speculative theory related to a drug, a clinical trial, or an adverse drug event were reported to the agency. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163, 178 (3d Cir. 2004) (observing that excessive risk-oriented regulation "can harm the public health . . . by encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments"). This Court therefore held that fraud-on-the-FDA claims "would exert an extraneous pull on the

scheme established by Congress, and it is therefore is pre-empted by that scheme." *Buckman*, 531 U.S. at 353. Under FDCA, responsibility rests with FDA-not the States-to balance the need to police fraud on the agency against the risk of excessive disclosures in drug approval applications. Allowing states to adjudicate fraud-on-the-FDA claims is incompatible with these uniquely federal objectives. For all these reasons, both legal and practical, the Second Circuit's decision to cabin *Buckman* to cases where the cause of action relies exclusively on fraud-on-the-FDA to impose liability under state law is erroneous.

Indeed, the Sixth Circuit, facing the same issue as the Second, correctly ruled that the Michigan fraud-on-the-FDA exception was preempted under *Buckman*. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). That court acknowledged that the Michigan law presented "a somewhat different legal regime from the one invalidated in *Buckman*." *Id.* at 965-66 (explaining that, under the Michigan law, the fraud-on-the-FDA question arose in the context of an exception to a defense, as opposed to "a specific cause of action for fraud on the FDA"). It nevertheless properly concluded that those differences were "immaterial" in that "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (citations and quotations omitted).

The court focused its analysis on *state litigation* of fraud-on-the FDA claims at issue here. "Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch meddling concerns that animated *Buckman*." *Id.* (emphasis added). Accordingly, whether *Buckman* preempts the Michigan exception will turn on whether the "plaintiff asks a state court to find . . . fraud on the FDA". *Id.* Because, in *Garcia*, the plaintiff sought a finding from the court that fraud occurred-and "did not offer any federal findings"-the state law products liability claim was preempted under *Buckman*. *Id.*; *see also Henderson v. Merck & Co., Inc.*, No. 04-CV-05987, 2005 WL 2600220, at *11 (E.D. Pa. Oct.

11, 2005) ("This Court follows the holdings of *Buckman* and *Garcia* and finds that . . . [Sections] 600.2946(5)(a) and (b) are preempted by the FDCA in most situations.").[5]

* * *

Buckman, in PhRMA's view, stands for the proposition that state law liability against a pharmaceutical manufacturer may not be dependent on a finding of fraud-on-the-FDA at least where FDA has not first made a finding of fraud on the agency with respect to the specific conduct at issue in that case. There can be no dispute that a clean split of circuit court authority exists because the Sixth Circuit accepts that principle and the decision below rejected it. This Court should accept the petition for writ of certiorari and resolve the split in favor of the Sixth Circuit. FDA simply cannot properly function under a regime where it shares authority over fraud in the approval process, whether stated as a cause of action or an exception to state law immunity, with the judges and juries of fifty states.

II. The Dispute Over The Preemption Rationale Underlying *Buckman* Is Not Limited To The Michigan Immunity Provision Or Even FDA-Related Litigation.

The implications of the Second Circuit's misinterpretation of *Buckman* are too important to allow this decision to remain in place. At least one other state has enacted a law like the Michigan provision at issue here. *See, e.g.*, Tex. Civ. Prac. & Rem. Code Ann. § 82.007. Other states permit litigation of fraud on the FDA as a basis for punitive damages on the FDA.

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5. A different analysis might be required where FDA has conclusively ruled that fraud occurred in a particular case, so that parallel state law remedies might reinforce the federal requirement. Such suits might not raise the same legal and policy concerns that arise when lay judges and juries are allowed either to speculate as to whether FDA would have reached that conclusion or are allowed drag FDA into the litigation as a fact or expert witness. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005); *see also id.* at 455 (Breyer, J., concurring) (adding that "the federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements").

See, e.g., Ariz. Rev. Stat. § 12-701; N.D. Cent. Code § 32-03.2-11; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 30.027; Or. Rev. Stat. Ann. § 30.927; Utah Code Ann. § 78-18-2. Under both types of statutory regime, liability rises and falls with the plaintiff's ability to prove to a lay judge or jury that fraud on the FDA occurred.

The validity of these statutes, like the Michigan statute at issue in *Garcia* and *Desiano*, therefore inevitably turns on the meaning of *Buckman*. *See, e.g.*, *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1171-74 (D. Ariz. 2005) ("Both a common law fraud-on-the-FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process."); *Ledbetter*, 2007 WL 1181991, at *5-6 ("Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas judge or jury to make the same inquiry would impinge on a uniquely federal issue."); *cf. In re Aredia & Zometa Prods. Liability Litig.*, No. 06-1760, 2007 WL 649266, at *9 (M.D. Tenn. Feb. 27, 2007) (explaining that "FDA will need to make a finding on the matter of fraud before the Plaintiffs will be entitled to recover punitive damages under New Jersey law").

Courts also have applied *Buckman* to common law claims based on fraud on the FDA. *See, e.g.*, *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001). In *Flynn*, the court held that, under *Buckman*, the FDCA impliedly preempted the plaintiff's state law fraud-on-the-FDA claim, which alleged that but for fraudulent misrepresentations made by Fen-phen's manufacturer during its approval process, the drug never would have been approved, and consequently, the plaintiff never would have been injured. *See id.* at 345. The court noted the similarities between the regulatory schemes that govern the approval of drugs and medical devices. *See id.* at 349. Because of these

similarities, subjecting drug manufacturers to the "50 States' tort regimes" would most likely have a disruptive effect on FDA's authority "to consistently police fraud within the agency's powers." *Id.* (citing *Buckman*, 531 U.S. at 348).

Moreover, a wealth of case law well beyond FDA-related litigation has built upon around *Buckman*. In *Nathan Kimmel, Inc., v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002), for example, the Ninth Circuit applied *Buckman* to a state suit claiming intentional interference with a prospective economic advantage. *Id.* at 1204-05. The basis of the state cause of action was that the defendant knowingly submitted false information to the EPA to obtain a particular label for a bag manufactured to contain an EPA-regulated pesticide. *Id.* Applying *Buckman*, the Ninth Circuit found that the plaintiff's state law claim was impliedly preempted by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 (1996). *Id.* at 1205.

As the Court explained, FIFRA is a "comprehensive regulatory scheme aimed at controlling the use, sale, and labeling of pesticides," and like FDA, EPA is empowered under the statute to deter and punish fraud using particular methods designed to "achieve a somewhat delicate balance of statutory objectives." *Id.* at 1203, 1206 (quoting *Buckman*, 531 U.S. at 348). The practical implications of allowing this suit to proceed would violate both the letter and the spirit of *Buckman*:

> [W]e are troubled that an applicant's disclosures under FIFRA, although not challenged by the EPA . . . may be judged illegal under state law. Such an approach would force FIFRA applicants to ensure that their disclosures to the EPA would satisfy not only standards imposed by that agency under federal law, but also the potentially heterogeneous standards propounded by each of the 50 states.

Id. at 1207.

Similarly, in *Zwiercan v. General Motors Corp.*, No. 02-3235, 2002 WL 31053838 (Pa. Com. Pl. Sept. 11, 2002), the plaintiff, after purchasing a car, brought an action against the car's manufacturer for breach of implied warranty and violation

of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL") alleging the manufacturer's failure to disclose defective front seats in the vehicle. *See id.* at *1. The court found that a state-law claim that involved the UTPCPL was preempted under *Buckman*: "Defendant is correct in stating that in so far as Plaintiff's UTPCPL claim seeks redress for misstatements to the [National Highway Traffic Safety Administration], it is a 'fraud on the agency' claim, which is properly preempted by federal law." *Id.* at *6. Accordingly, "because the Plaintiff cannot use the UTPCPL to enforce an alleged fraud on a federal agency, Defendant's Motion for Summary Judgment on this issue is granted." *Id.*

Cases such as these are legion. *See, e.g., Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 722 (E.D. Tenn. 2001) (holding that, under *Buckman*, the comprehensive United States Department of Energy (DOE) regulations impliedly preempted the plaintiff's state law civil conspiracy claim, since allowing the claim to proceed would inevitably "conflict[ ] with the DOE's ability to set nuclear policy consistent with its own judgment and objectives"); *McCall v. Pacificare of Cal., Inc.*, 21 P.3d 1189, 1199 n.9 (2001) ("To the extent the [plaintiff's] complaint alleges fraud on the [Health Care Financing Administration], defendants may, on remand, assert it is preempted under the rule in *Buckman*."); *Andrx Pharms., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1369-70 (S.D. Fla. 2001) (holding that, under *Buckman*, the plaintiff's claims for deceptive and unfair practices, tortious interference with business relationships, and negligence per se were impliedly preempted by the Hatch-Waxman Act in the FDCA because all of these claims necessarily rely on violating the Act's patent listing requirements), *vacated on other grounds*, 276 F.3d 1368 (Fed. Cir. 2002); *Beck v. Koppers, Inc.*, Nos. 3:03CV60-P-D, 3:04CV160-P-D, 2006 WL 2228910, at *1 (N.D. Miss. Apr. 7, 2006) (rejecting state law fraud-on-the-EPA conspiracy claim because, "[g]iven the ruling in *Buckman*, the plaintiff may not recover for any alleged fraud against the [EPA] under the rubric of a state-law conspiracy claim").

Not all lower courts disagree, however, with the logic of *Desiano*. *See Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470

(Fed. Cir. 1998). In that case, the Federal Circuit confronted a state law unfair competition claim alleging that Exxon obtained a patent "by inequitable conduct" before the PTO. *Id.* at 1472. Exxon defended arguing that such a claim was preempted. *See id.* at 1473. The Federal Circuit rejected this argument, holding that the state law claim is not "preempted by the federal patent law, even if it requires the state court to adjudicate a question of federal patent law, provided the state law cause of action includes additional elements not found in the federal patent law cause of action and is not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." *Id.*; *but see id.* at 1480 (Lourie, J., dissenting) ("Permitting a state law claim to be based essentially on an assertion of inequitable conduct . . . leads to the potential of conflicting results, an eventuality that preemption is intended to avoid.").

The court reached this conclusion notwithstanding a long line of authority sustaining federal exclusivity in the patent context. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964) (holding that the uniquely federal character of the patent system not only prevented states from encroaching upon it directly, but also prevented states "under some other law, such as that forbidding unfair competition, [from] giv[ing] protection of a kind that clashes with the objectives of the federal patent laws"); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1998) ("[O]ur past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."); *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1357 (Fed. Cir. 1991) (preempting a Michigan state tort action alleging "inequitable or other unsavory conduct of parties to proceedings in the Patent and Trademark Office" because "the PTO procedures themselves provided a remedy for Abbott's malfeasance").

As the Federal Circuit had explained in *Abbott Laboratories*, "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures

of the PTO, 'under the guise of a complaint sounding in tort' . . . and is contrary to Congress' preemptive regulation in the area of patent law." *Id.* at 1357 (quoting *Gilbert v. Ben-Asher*, 900 F.2d 1407, 1411 (1990)). The Federal Circuit's failure to adhere to *Stiffel* and *Bonito Boats*, and its own opinion in *Abbott Laboratories*, parallels the Second Circuit's failure to abide *Buckman*. Both decisions reward creative state legislatures with freedom to interfere in uniquely federal issues, such as patent and pharmaceutical regulation, that this Court has made clear should be free from state superintendence.

Accordingly, allowing the decision below to remain good law and provide a roadmap to evading *Buckman* will cast a shadow over an array of federal regulatory regimes. To the extent that the Second Circuit decision becomes precedential, a State need only enact a statute permitting liability to arise for federally-mandated actions, provide a defense negating that liability and include an exception for fraud on the federal agency to render *Buckman* a nullity. For example, Pennsylvania could simply enact statutory liability for defective automobile designs, create a National Highway Traffic Safety Administration compliance defense (to the extent that NHSTA has approved the design), but override the defense if approval were procured through fraud on the federal agency, and then argue that the *Zweircan* decision, *supra*, p. 10 should be set aside. *Buckman* would be a trivial addition to the law if stood for a proposition so narrow that states could avoid its mandate with such ease. Granting the petition, and reversing *Desiano* thus would not only resolve an issue important to pharmaceutical regulation, it would provide the Court an opportunity to more broadly set the course of the lower courts on this important aspect of federal preemption.

CONCLUSION

For all of the foregoing reasons, and for the reasons set forth in the petition, the Court should grant the petition on the question presented and reverse the decision of the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

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